STATE OF FLORIDA
DEPARTMENT OF CHILDREN AND FAMILIES
OFFICE OF APPEAL HEARINGS

[redacted]

APPEAL NO. 16F-00490 and 16F-00491

PETITIONER,

Vs.

CASE NO.

AGENCY FOR HEALTH CARE ADMINISTRATION
CIRCUIT: 13 Hillsborough
UNIT: AHCA

RESPONDENT.
_____/

FINAL ORDER

Pursuant to notice, the undersigned convened a telephonic administrative hearing in the above-referenced matter on February 17, 2016 at 3:09 p.m.

APPEARANCES

For the Petitioner: [redacted] Quality Specialty Pharmacy

For the Respondent: Stephanie Lang, Agency for Health Care Administration

STATEMENT OF ISSUE

At issue is whether the Agency properly denied Petitioner's request for prescription medication [redacted] Petitioner held the burden of proof in this matter by a preponderance of the evidence.

PRELIMINARY STATEMENT

The Agency for Healthcare Administration (AHCA or Agency) is responsible for administering Florida's Medicaid Program. AHCA contracts with managed care plans to

provide services, including pharmacy services, to Medicaid recipients in Florida. The managed care plans provide prior authorization reviews for requested services.

Petitioner was not present and did not provide testimony. She was represented by a representative from her pharmacy. [redacted] was present as Petitioner's representative and witness. [redacted] Pharmacist, Quality Specialty Pharmacy, provided testimony for Petitioner. Respondent's witnesses were Susan Frischman (Senior Compliance Analyst), Debra Smith (Director of Pharmacy), and Dr. Marc Kaprow (Executive Director of the Long Term Care Program) with United Healthcare.

Respondent submitted fourteen exhibits, marked and entered as Respondent's Exhibits 1 through 14, into evidence. The hearing officer took administrative notice of Sections 409.910, 409.912, 409.962 through 409.965, 409.973, and 409.91195 of the Florida Statutes (2015), Florida Administrative Code Rules 59G-1.001, 1.010, 4.255, 4.250, and the Medicaid Prescribed Drug Services Coverage, Limitations and Reimbursement Handbook (July 2014).

FINDINGS OF FACT

Based upon the oral and documentary evidence presented at the final hearing and on the entire proceeding, the following Findings of Fact are made:

1. Petitioner is an adult female diagnosed with chronic [redacted] Type 1a. She is treatment naïve (has not been treated before) and has a [redacted] Scores can range from [redacted] with [redacted] being no [redacted] She has a high viral load. She is seeing a specialist physician for her treatment. She is a member of United Healthcare's Medicaid managed care plan.

2. Petitioner's treating specialist submitted a preauthorization request to the Agency for [redacted] on or about September 14, 2015. The request was denied by notice dated September 15, 2015. The notice indicated that it was denied because there was no indication Petitioner was being treated for [redacted]

3. Petitioner's specialist requested an expedited reconsideration of the denial, on or about October 12, 2015. He acknowledged in his letter and supporting documentation that Petitioner does not have [redacted], but requested reconsideration due to the drug therapy's effectiveness. In support of this request, he provided a letter of medical necessity citing to guidelines, medical journals, and studies. He also provided Petitioner's clinical notes and lab results to support the request for [redacted]

4. The plan reviewed the submitted documentation and upheld the denial. The denial notice dated October 15, 2015, stated in relevant part:

> …This decision was made per the UnitedHealthcare Florida Community & State Guideline Viekira. You have asked for [redacted] is given when you have [redacted] The notes we received from your doctor do not show you have [redacted] Please speak with your doctor about this.

5. The plan denied the preauthorization request for [redacted] because Petitioner's condition must meet certain criteria to be approved for these particular drugs. Based on the plan's review of Petitioner's medical records, Petitioner's condition does not meet the specific criteria for [redacted]

6. Petitioner requested a fair hearing to dispute the denial. She contends that she should be granted the [redacted] because she has a risk of developing

[redacted]f left untreated. She has had high iron levels in the past, which may be explained by concurrent gallstones at the time. She has a family history of cancer, which can lead to a greater risk of cancer in general for this Petitioner. She argues that professional medical societies have created guidelines for the drugs' use which indicates use at earlier [redacted] is beneficial, and those guidelines should be adopted here.

CONCLUSIONS OF LAW

7. The Department of Children and Families Office of Appeal Hearings has jurisdiction over the subject matter of this proceeding and the parties, pursuant to Section 120.80, Florida Statutes.

8. The Florida Medicaid program is authorized by Chapter 409, Florida Statutes, and Chapter 59G, Florida Administrative Code. The program is administered by the Agency.

9. This hearing was held as a de novo proceeding pursuant to Florida Administrative Code Rule 65-2.056.

10. The standard of proof needed to be met for an administrative hearing is by a preponderance of the evidence, as provided by Florida Administrative Code Rule 65-2.060(1).

11. Section 409.912, Florida Statutes (2015) provides that AHCA shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To this end, the Agency has contracted with managed care organizations to provide medical coverage to enrolled recipients.

12. The Florida Medicaid Provider General Handbook (Provider Handbook) – July 2012 is incorporated by reference in Florida Administrative Code Rule 59G-5.020. In accordance with the Florida law, the Provider Handbook discusses managed care coverage, stating on page 1-27:

> Medicaid contracts with Health Maintenance Organizations (HMOs) to provide prepaid, comprehensive, cost-effective medical services to enrolled Medicaid recipients.
>
> Medicaid pays each HMO a monthly capitation fee for managing and providing care to each enrolled recipient. In accordance with certain contractual agreements with Medicaid, the HMO provides a specified, comprehensive package of medical services for this monthly Medicaid fee.
>
> Medicaid HMOs are also required to provide quality and benefit enhancements and can provide other expanded benefits as described in this section.

13. Page 1-30 of the Provider Handbook states: "An HMO's services cannot be more restrictive than those provided under Medicaid fee-for-service."

14. All Medicaid covered services must be "medically necessary" as defined by law. Florida Administrative Code, 59G-1.010(166), defines medical necessity, as follows:

> "Medically necessary" or "medical necessity" means that the medical or allied care, goods, or services furnished or ordered must:
> (a) Meet the following conditions:
> 1. Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
> 2. Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs;
> 3. Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
> 4. Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide; and
> 5. Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

> (c) The fact that a provider has prescribed, recommended, or approved medical or allied care, goods, or services does not, in itself, make such care, goods or services medically necessary or a medical necessity or a covered service.

15. In order to determine "medical necessity," the Agency has created guidelines. The guidelines are "consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational." For prescription drugs, the managed care plan has adopted the Agency's guidelines.

16. For prescription drugs, Sections 409.912(8)(a)(14) through 409.912(16), Florida Statutes (2015), are instructive. Pursuant to Section 409.912(8)(a)(14), "the agency may require prior authorization for Medicaid-covered prescribed drugs." Section 409.91195 describes how the Agency creates and maintains such a process and creates the guidelines through a committee.

17. The Prescribed Drug Services Coverage, Limitations and Reimbursement Handbook (July 2014) ("The Handbook") is promulgated into law by Florida Administrative Code Rule 59G-4.250. The Handbook echoes the information from the Florida Statutes.

18. The Agency has the authority to manage its prior authorization process, including establishing criteria for approval. It established specific criteria for Viekira Pak and Ribavirin. The Medicaid drug criteria for [redacted] require at least Stage [redacted] for approval. Petitioner's scores show her [redacted] is not that advanced, so she does not meet the established criteria for [redacted] and [redacted] The guidelines account for co-morbid diseases and other issues which would create a medical need for the drugs. There are no exceptions to the guidelines for

special cases not included in the criteria. Petitioner is entitled to all the benefits, support, and care the State of Florida may furnish to a person in her circumstances, except when eligibility is limited by law, such as here.

19. Petitioner argues that the medication should be approved because it has been shown to be useful in people with less extreme [redacted] Additionally, some professional medical organizations use guidelines which support the drugs' use in [redacted] cases. However, the fair hearing process is not the forum to challenge existing rules. The fair hearing process is to review the Agency's action based on the existing rules and regulations. The hearing officer must determine whether the "decision on eligibility or procedural compliance was correct at the time the decision was made." Fla. Admin. Code R 65-2.056(3). Based on the rules and regulations in effect at the time the decision was made, the Agency properly denied Petitioner's request. There is no rule or exception permitting the Agency to authorize the [redacted] for a recipient who does not meet the established guidelines. There is no rule or exception permitting the hearing officer to create or change Agency rules or policy to make such exceptions.

20. Petitioner did not meet her burden of proof to show that she meets the criteria to receive this medication. She is encouraged to work with her physician and the Agency to find a medication that will meet her needs and can be approved.

21. After careful review of the evidence submitted and the relevant laws set forth above, the undersigned finds the Agency's action in this matter was correct.

DECISION

Based upon the foregoing Findings of Fact and Conclusions of Law, the Petitioner's appeal is hereby DENIED and Agency's action is AFFIRMED.

NOTICE OF RIGHT TO APPEAL

This decision is final and binding on the part of the agency. If the petitioner disagrees with this decision, the petitioner may seek a judicial review. To begin the judicial review, the petitioner must file one copy of a "Notice of Appeal" with the Agency Clerk, Agency for Health Care Administration, 2727 Mahan Drive, Tallahassee, FL 32308-5403. The petitioner must also file another copy of the "Notice of Appeal" with the appropriate District Court of Appeal. The Notices must be filed within thirty (30) days of the date stamped on the first page of the final order. The petitioner must either pay the court fees required by law or seek an order of indigency to waive those fees. The petitioner is responsible for any financial obligations incurred as the agency has no funds to assist in this review.

DONE and ORDERED this 22 day of February, 2016,

in Tallahassee, Florida.

Danielle Murray
Hearing Officer
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Copies Furnished To: [redacted] Petitioner
Don Fuller, Area 6, AHCA Field Office Manager